

II. REMARKS

A. Status of the Claims

Claims 35-44 are currently pending. Claims 1-34 have been cancelled without prejudice. Claim 35 has been amended without prejudice. New claims 36-44 have been added. Support for new claims 36-44 can be found throughout the application, e.g., the originally filed claims. It is respectfully submitted that no matter has been added by virtue of this amendment.

B. Rejection under 35 U.S.C. § 103(a)

In the Office Action, the Examiner rejected claims 3, 6, 16, 17, 19, 20, 22-25, 27-33, 34 and 35 under 35 U.S.C. § 103(a) as being unpatentable over the combined disclosures of 6,253,920 B1 to Kallgren (hereinafter "Kallgren"); U.S. Patent No. 6,365,184 to Depui et al. (hereinafter "Depui et al."); and WO 88/02342 to Eek (hereinafter "Eek").

As claims 1-34 have been cancelled, Applicants submit the following remarks as applied to amended claim 35 and new claims 36-44.

In making the rejections, the Examiner stated that "[i]t is the position of the examiner that one of ordinary skill would be motivated to combine the disclosures of Kallgren, Depui et al., and Eek in order to create a packaging system comprising a proton pump inhibitor in combination with a non-steroidal anti-inflammatory drug." The Examiner further stated that "[i]t is the position of the examiner that one of ordinary skill in the art would recognize that the aims of the Kallgren, Depui et al., and Eek are similar in the area of improving patient compliance," and "[a]s the disclosed invention of Kallgren is not limited to any particular types of drugs to be packaged, one of ordinary skill can expect to create a drug pack comprising dosages of lansoprazole and naproxen in accordance with a combination dosage regimen with a reasonable expectation of success."

This rejection is traversed. It is respectfully submitted that Kallgren, Depui et al., and Eek are improperly combinable, and one of ordinary skill in the art would not be motivated to combine Kallgren, Depui et al. and Eek to arrive at the invention as recited in the present claims.

In support of this position, the following are noted with respect to each reference

Kallgren states the following at column 3, lines 23-28:

It will be appreciated that the blister pack can consist of at least two differently shaped sets of blisters, each set containing a different drug. This type of blister pack is especially useful for packing, in one blister pack, two drugs that should be administered in combination, for example omeprazole and antibiotics.

Depui et al., state the following at column 2, lines 36-41:

. . . administration of two or even more different tablets to the patient is not convenient or satisfactory to achieve the most optimal results. The present invention now provides new oral dosage forms comprising two or more different active substances combined in one fixed unit dosage form, preferably a tablet.

Eek states the following at page 1, lines 5-7:

The present invention is related to a novel drug pack, in general with the same basic construction as the tablet cards or "blister packs" which today are in extensive use today.

Eek further states the following at page 1, line 34 to page 2, line 5:

Combination preparations are however frequently connected with limitations and drawbacks which causes the[m] often not to provide the best possible treatment. A significant problem is the insufficient flexibility of combination preparations. Different patients may require different combinations of substances or different dosages of the various substances.

It is respectfully submitted that Depui et al. is directed to two or more active

substances in a fixed unit dosage form (i.e., two drugs in the same dosage form). In contrast, it is respectfully submitted that when Kallgren describes the combination of two drugs, Kallgren describes the packaging of two different drugs in different dosage forms in two differently shaped sets of blisters. In further contrast to Depui et al., Eek asserts that when treatment with a plurality of drugs is desired, a combination pack assembled from two or more packs may be prepared. In such a combination pack of Eek, the drugs are in separate unit dosage forms and not a fixed unit dosage form (e.g., such as a single dosage form containing two or more active substances as described in Depui). Therefore, it is respectfully submitted that in the very least, Depui et al is not properly combinable with Kallgren nor Eek.

Furthermore, it is respectfully submitted that Kallgren and Eek are also not properly combinable. As noted above, Eek describes the use of blister packs having, in general, “the same basic construction as the tablet cards or ‘blister packs’ which today are in extensive use.” See Eek at page 1, lines 5-7. Eek was filed in 1986, and published in 1988 (prior to the filing date of Kallgren). It is respectfully submitted that the basic construction of the tablet cards or “blister packs” of Eek are similar to the conventional blister packs having the problems referred to by Kallgren in the Background of the Invention section at column 1, lines 33-42 of Kallgren. An object of Kallgren is to find a solution to the problems with “conventional blister packs” (e.g., similar to those in Eek), which is achieved by purportedly novel blister packs described in Kallgren. In view of the differences in the blister packs of Kallgren and Eek, it is respectfully submitted that the Kallgren is not properly combinable with Eek.

Furthermore, the Examiner is again reminded that:

“[a] prior art reference may be considered to teach away when ‘a person of ordinary skill, upon reading the reference would be discouraged from the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.’” See *Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH*, 45 USPQ2d 1977, 1984 (Fed. Cir. 1998).

Therefore, it is respectfully submitted that Depui et al. teach away from the present invention in column 2, lines 36-38, by stating that “administration of two or even more different tablets to the patient is not convenient or satisfactory to achieve the most optimal results.”

Further, it is respectfully submitted that in view of Depui et al., one of ordinary skill in the art would not be motivated to administer active substances which are combined in a fixed unit dosage form in separate unit dosage forms as Depui et al. describe administration of two or more tablets to a patient as not convenient or satisfactory to achieve the most optimal results. Further, one of ordinary skill in the art would not be motivated to combine Depui et al. with Kallgren or Eek, as in view of Depui et al., one of ordinary skill in the art would not be motivated to keep two drugs in two separate dosage forms as recited in the present claims (and as recited in Kallgren and Eek) and would be discouraged from this path.

In view of the above arguments, the Examiner is respectfully requested to withdraw the 35 U.S.C. § 103(a) rejection.

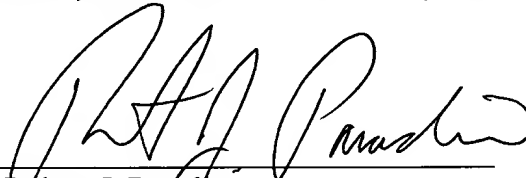
III. CONCLUSION

In view of the arguments presented, it is respectfully submitted that this application is now in condition for allowance.

An early and favorable action on the merits is earnestly solicited. The Examiner is invited to contact the undersigned at the telephone number provided below if he believes that a telephonic interview will advance the prosecution of this application.

Respectfully Submitted,

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